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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,899	12/29/2000	Frank J. Bunick	MCP-0262	9623

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EXAMINER	
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ART UNIT	PAPER NUMBER
1611	

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06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/752,899	BUNICK ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *4-7-09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,8,9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8,9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment, Declaration and response dated 4-07-09 is acknowledged. New claim 14 has been added. Claims 1-3, 5, 8-9, 11-14 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-7-09 has been entered.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5, 8-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,667,050 B1 to Boissonneault et al ('050) in view of US 3,619,292 to Brouillard ('292) OR US 6,667,050 B1 to Boissonneault et al ('050) and US 4,684,534 to Valentine ('534) in view of US 3,619,292 to Brouillard ('292).

'050 teach a chewable tablet composition comprising an active ingredient and carriers such as dextrose, microcrystalline cellulose, polyvinylpyrrolidone etc (all of which are claimed in the instant) and sucralose (examples). The examples of '050

contain sucralose as a sweetener. '050 teach the same binders and disintegrants that are also claimed in the instant invention but fail to teach dextrose monohydrate. The compositions of '050 do not necessarily require fat, non-saccharide water soluble binder or aspartame (claims 1, 8 and 11) (examples 3 and 6) and thus meet the claimed limitation. The examples of '050 teach the claimed disintegrants and lubricants (see examples) and other auxiliary ingredients of claim 12 (examples and col. 5-6).

'050 teach dextrose but not dextrose monohydrate and the claimed particle sizes.

'292 teach forming a free-flowing tablet containing a binder or a binder-filler, which is a sugar granule. The sugar granule comprises aggregates of cohered microcrystals of dextrose (abstract and col. 1, L 1- 20). According to '292 dextrose hydrate provides more advantages when employed in direct compression than in wet granulation or dry granulation because it produces a cooling effect when dissolved in the mouth, which is highly desirable for a tableted food or a pharmaceutical and can also enhance the flavor in the tablet (col. 2, L 10-35), particularly chewable drug tablets (col. 5, KL 55-58).

Valentine '534 teaches a chewable tablet composition comprising excipient base materials such as carbohydrate based agglomerate materials including dextrose, dextrose monohydrate, fructose, sucrose etc., which are held together by small quantities of binding materials such as maltodextrin (col. 2-3). The carbohydrate agglomerates are in the size range of 20 to 100 microns (col. 4, L 29-35 & col. 9, lines 20-42) and particulate active agent having a particle size of about 50 microns (col. 4). '534 teaches at least 25% by weight of the carbohydrate agglomerate and in particular,

claim 3 recites 90% to 99% by weight for a quick melting tablet. Valentine clearly states that the tablet is prepared by direct compression (col. 1, L 57-63).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that the particulate agglomerated carbohydrates or granules such as dextrose or dextrose monohydrate (of Valentine '534 or '292) in the composition of '050 for preparing directly compressed tablets because Valentine '534 teach that dextrose and dextrose monohydrate are equally effective for compressibility, the tablets are highly compressible and also the tablets readily dissolve in minimal amounts of water in the mouth thus quickly liquefying of the active agent. Further '292 also teach that dextrose monohydrate particles disintegrate very quickly in the mouth and enhance the flavor of the tablet.

New claim 14 recites the same limitation i.e., the ratio of dextrose monohydrate to sucralose, which was presented previously in claim 1. Claim 1 has now been amended to delete the limitation. With respect to the ratio of dextrose monohydrate and sucralose, the example compositions of '050 contain high amounts of dextrose compared to the sweeteners such as sucralose and aspartame. In this regard, applicants have not established any unexpected advantage with the claimed ratio and accordingly choosing the appropriate amounts of binders and sweeteners to achieve the desired effect would have been within the scope of a skilled artisan.

Response to Arguments

Applicant's arguments and the declaration filed 4-17-09 have been fully considered but they are not persuasive.

Applicants argue that as noted in the Declaration under 37 C.F.R. § 1.132 of Frank Bunick, it is not obvious to take a chewable tablet of Boissonneault et al., formulated with a high intensity sweetener and dextrose, and substitute the dextrose with dextrose monohydrate as suggested in the present Office Action. It is argued that the combination of dextrose monohydrate with a high intensity sweetener is known to cause stability issues, specifically, tablets formed with dextrose monohydrate and a high intensity sweetener have been known to exhibit discoloration and browning as the tablets age. It is argued that Dr. Bunick points out in his declaration that aspartame, a high intensity sweetener that is an amine based compound will react with dextrose over time, resulting in discoloration and browning of tablets formulated as such. By exposing the tablets to elevated temperature conditions, the tablets are stressed and the bound water in the dextrose monohydrate is released. This facilitates the reaction within the tablets between the dextrose, active ingredients, and/or excipients (i.e., inactive ingredients), which produces undesirable stability issues. Therefore applicants conclude that one skilled in the art would not favor the combination of dextrose monohydrate and a high intensity sweetener. Applicants further state that the present inventors have surprisingly discovered that when sucralose is used as the high intensity sweetener, that it does not react with dextrose in the presence of increased levels of water and tablets formulated with sucralose and dextrose monohydrate do not exhibit discoloration or browning. Therefore, Applicants submit that Claim 1 is patentable over Boissonneault et al., Brouillard et al. and/or Valentine, since there is no motivation to combine the references in the proposed manner. It is argued that Claim 12 is similar to Claim 1 and

also includes the unique combination of dextrose monohydrate and sucralose. For at least the reasons stated above for Claim 1, Claim 12 is patentable over Boissonneault et al., Brouillard et al. and/or Valentine, since there is no motivation to combine the references as proposed.

Applicants' argument and the declaration of Bunick have been considered but not found persuasive. Instant claims require sucralose, dextrose monohydrate and an active ingredient, in a chewable tablet that is free of fat and free of non-saccharide, water-soluble polymeric binders. While applicants argue that the combination of aspartame and dextrose monohydrate leads to discoloration, the primary reference teaches the claimed sucralose and the rejection of record provides motivation to combine dextrose monohydrate with sucralose and not aspartame. If applicants' arguments that sucralose instead of aspartame in combination with dextrose monohydrate do not exhibit discoloration and browning, then for the same reason instant combination also does not result in discoloration and browning. Further, instant claims are directed to a composition and not a method of stabilizing dextrose monohydrate by the addition of sucralose. The rejection of record provides the requisite motivation to add dextrose monohydrate to sucralose i.e., prepare directly compressed tablets because Valentine '534 teach that dextrose and dextrose monohydrate are equally effective for compressibility, the tablets are highly compressible and also the tablets readily dissolve in minimal amounts of water in the mouth thus quickly liquefying of the active agent. Further '292 also teach that dextrose monohydrate particles disintegrate very quickly in the mouth and enhance the flavor of the tablet. Thus, even though applicants identify a

different advantage of stabilizing dextrose monohydrate with sucralose the argued property is expected from the combination of prior art that suggests adding dextrose monohydrate instead of dextrose in compressible and chewable tablets that also contain sucralose as a sweetener. The prior art provides requisite motivation for preparing compressible tablets containing dextrose monohydrate. Therefore, the arguments that Boissonneault lacks direct compression of dextrose monohydrate and Brouillard and Valentine lack sucralose, amount to arguing references individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The declaration submitted by Frank Bunick also explains the disadvantages of combining dextrose monohydrate with high intensity sweetener, aspartame, in terms of discoloration and browning of the tablets caused by the release of the high levels of bound water in dextrose monohydrate at elevated temperatures of storage. The declaration is accompanied by the product sheet of dextrose monohydrate powder USP. While the declaration has been considered it was not found persuasive because firstly, instant rejection does not propose combining dextrose monohydrate with aspartame and instead the primary reference clearly teaches sucralose, a preferred sweetener, by applicants own admission. Thus, any disadvantages explained in the declaration of Bunick would not have been seen with the combination of the references of record. Further, the rejections also suggest combining dextrose monohydrate with the teachings

of Boissonneault for the advantages of compressibility of the tablet and chew ability, and even though the motivation of combining the two components is not the same as that proposed by applicants, the stability argued by Bunick would be expected by the combination of references of record.

While applicants did not present arguments regarding other limitations such as ratios of sucralose and dextrose monohydrate, the arguments were made in the previous responses and the response to such arguments in the last final action (1-7-09) are reproduced below:

Applicants' argue that instant claims have been amended to recite the specific range of sucralose i.e., 0.5% to 5% and a ratio of dextrose monohydrate to sucralose of 25:1. It is argued that the cited references fail to teach the above limitations. It is argued that Boissonneault in example 11 teaches 0.017% sucralose and 58.3% dextrose and that even if one were to substitute dextrose monohydrate for dextrose one would not arrive at the claimed range. Applicants' arguments are not persuasive because the amount of dextrose of Boissonneault i.e., 58.3% is within the claimed range and the rejection above provides the requisite motivation to substitute dextrose monohydrate for dextrose, the rationale of which has not been argued. With respect to the amount of sucralose, it is agreed that Boissonneault teaches sucralose as a sweetener. A skilled artisan would have been able to adjust the amount of a sweetener in a tablet composition depending on the level of sweetness desired. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or

temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The prior art teaches dextrose (monohydrate) and sucralose for their binder and sweetener effect and in the absence of any unexpected advantage with the claimed ratio of the two components, it would have been within the scope of a skilled artisan to optimize the individual amounts of the components with an expectation to achieve the art recognized effect. Therefore the arguments regarding the patentability of instant claims over Boissonneault, Brouillard et al and Valentine are not found persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
June 21, 2009